COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 16.12.2008
C(2008)8734

NOT FOR PUBLICATION

COMMISSION DECISION

of 16.12.2008

on the renewal of the marketing authorisation for the medicinal product for human use "Faslodex - Fulvestrant", granted by Decision C(2004)851

(ONLY THE ENGLISH TEXT IS AUTHENTIC)

COMMISSION DECISION

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on the renewal of the marketing authorisation for the medicinal product for human use "Faslodex - Fulvestrant", granted by Decision C(2004)851

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by AstraZeneca UK Limited, on 18 June 2008, under Article 14(2) of Regulation (EC) No 726/2004 with a view to the renewal of the marketing authorisation for the medicinal product "Faslodex - Fulvestrant"

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2], and in particular Article 61(3) thereof,

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 23 October 2008,

Whereas:

(1) On the basis of a re-evaluation by the Agency of the risk-benefit balance following the consideration of a consolidated file, it appears that the medicinal product "Faslodex - Fulvestrant", entered in the Community register of medicinal products under number(s) EU/1/03/269/001 and authorised by Commission Decision C(2004)851 of 10 March 2004, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[3].

(2) The marketing authorisation which expires on 12 March 2009 should therefore be renewed.

(3) AstraZeneca UK Limited submitted, under Article 61(3) of Directive 2001/83/EC, a notification(s) for changes to an aspect of the labelling or the

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1 OJ L 136, 30.4.2004, p. 1.
2 OJ L 311, 28.11.2001, p. 67.
3 OJ L 311, 28.11.2001, p. 67.

package leaflet, which has (have) not yet been included in Decision C(2004)851 of 10 March 2004.

(4) The marketing authorisation should be updated, and Decision C(2004)851 amended accordingly.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2004)851 of 10 March 2004 which expires on 12 March 2009 is renewed.

Article 2

Decision C(2004)851 is amended as follows:

1) The following list of notifications for changes to an aspect of the labelling or the package leaflet is added to the updated marketing authorisation;

Application number	Annex (EU numbers affected)
EMEA/H/C/540/N/013	IIIB (EU/1/03/269/001)

2) Annex I is replaced by the text set out in Annex I to this Decision;

3) Annex II is replaced by the text set out in Annex II to this Decision;

4) Annex III is replaced by the text set out in Annex III to this Decision.

Article 4

This Decision is addressed to AstraZeneca UK Limited, Alderley Park, Macclesfield, Cheshire, SK10 4TG United Kingdom.

Done at Brussels, 16.12.2008

For the Commission
Heinz ZOUREK
Director-General